APPENDIX G

ORR BIOSOLIDS LAND APPLICATION SITES HUMAN HEALTH RISK ASSESSMENT

ACRONYMS

COC	constituent of concern
CSF	cancer slope factor
DOE	U.S. Department of Energy
EA	environmental assessment
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
LET	linear energy transfer
LOAEL	Lowest Observed Adverse Effect Level
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No Observed Adverse Effect Level
NRC	National Research Council
ORNL	Oak Ridge National Laboratory
ORR	Oak Ridge Reservation
POTW	Publicly Owned Treatment Works
RESRAD	Residual Radioactivity computer model
RfC	reference concentration
RfD	reference dose
TDEC	Tennessee Department of Environment and Conservation

1. HUMAN HEALTH RISK ASSESSMENT

1.1 INTRODUCTION

This appendix presents a human health risk assessment and is provided as a component of the environmental assessment (EA) for the U.S. Department of Energy (DOE) action to manage sewage sludge by land application on federal land. The ongoing land application operation, regulated by the state of Tennessee under U.S. Environmental Protection Agency (EPA) authority, is not part of the proposed action described in the EA. No human health risk evaluation exists for the ongoing operation; therefore, this risk evaluation of the ongoing sludge management practice is presented as an appendix to the EA.

Municipal sewage sludge is regulated by EPA under the authority of the Clean Water Act. EPA has delegated authority for local sludge management to the Tennessee Department of Environment and Conservation (TDEC), which has responsibility for compliance. However, the city of Oak Ridge must still comply with 40 *CFR* 503 regulations and report to the EPA Region IV annually.

The city of Oak Ridge has been applying sanitary sewage sludge to selected sites on the Oak Ridge Reservation (ORR) since 1983. The Oak Ridge Y-12 Plant is a standard industrial customer of the city of Oak Ridge. The Y-12 Plant is permitted to discharge sanitary sewage to the city, under the city's industrial pretreatment charter, with prescribed sanitary sewage discharge limits and restrictions similar to those of other industrial sewage generators located in the city. Final management of the treated sludge is by land application on federal land.

In addition to the Oak Ridge Y-12 Plant, which is a DOE facility that uses radioactive materials, there are several other state of Tennessee-licensed industrial facilities that also release radioactive materials into the Oak Ridge sanitary sewer system (e.g., American Ecology Recycle Center, Scientific Ecology Group, Manufacturing Sciences Corporation). With certain exceptions for patients of the local hospital, all facilities must meet the same acceptance criteria as other industrial users of the city's sewage treatment plant. In addition to radioactive materials, small quantities of inorganic compounds may also be released to the sewer.

Sanitary sewage sludge also contains high concentrations of human pathogens. Bacterial, viral, parasitic, and fungal pathogens in municipal sewage sludge have been identified as potential hazards to human health (WHO 1981; Kowal 1982,1985). EPA has evaluated the risk from exposure to pathogens in land-applied sludge separately (EPA 1988, 1989a) and determined that the risk of exposure to pathogens in sludge-amended soils is minimal.

During the treatment process, constituents may become concentrated in the sludge. The health effects of exposure to sludge containing low levels of radionuclides or chemicals need to be estimated in order to evaluate the safety of the current practice. Therefore, risks associated with exposure to low levels of radionuclides and chemicals in sanitary sewage sludge are addressed in this appendix.

This risk assessment has been performed in accordance with current risk assessment guidance provided by the EPA including: *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A)* (EPA 1989b), *Supplemental Guidance* (EPA 1991a), and *Exposure Factors Handbook* (EPA 1990).

The report organization is as follows. Section 1 provides an overview of the risk assessment process. Section 2, Identification of Constituents of Concern, describes the COCs that are evaluated in this risk assessment and their site-specific media concentrations. Section 3, Toxicity Assessment, describes the determination of toxicity or dose-response values for the COCs. Section 4, Exposure Assessment, identifies potential receptors and describes how potential exposure pathways were identified and exposure conditions were estimated. Section 5, Risk Characterization, combines the data generated in the Exposure Assessment with the data presented in the Toxicity Assessment to derive estimates of potential risk posed by COCs in sludge-amended soils. Section 6, Uncertainty Analysis, discusses the major sources of uncertainty associated with each step of the human health risk assessment process. Section 7 presents the Summary and Conclusions.

1.2 SITE-SPECIFIC RISK ASSESSMENT APPROACH

The purpose of this human health risk assessment is to evaluate the extent to which compounds present in the Publicly Owned Treatment Works (POTW) sewage sludge may potentially present a risk to human health, either during the application process or after blending with site soils. Quantitative estimates of potential carcinogenic and noncarcinogenic risks are made and presented for potential exposures associated with probable use of the land application site.

The predominant current and expected future land uses on the ORR are industry, forestry, environmental research, and agriculture. Nearly all workers are employed and located at the three major DOE industrial and research facilities [Oak Ridge National Laboratory (ORNL), Y-12 Plant, K-25 Site]; only a small percentage of work (environmental research, silviculture, and agriculture) is performed on the ORR outside of these facilities. Access is restricted on the entire ORR, including the three major facilities. All land application sites are within the ORR. The focus of this risk assessment is the evaluation of the potential risk to human health due to the presence of constituents in treated sewage sludge and ultimately in site soils at the land application sites. Because access is restricted at each of the locations, surface soils are not generally available for direct human contact by the general public.

Trained sludge workers would be present at the land application site during application of sewage sludge to soil. Exposure could occur during application; however, procedures are currently in place to limit exposure to workers during application. Theoretically, it is possible for a trespasser to have intermittent contact with the sludge-amended soils, although because of current access restrictions the potential for this exposure scenario to occur is limited. If it did occur, it is likely that it would be infrequent and that the exposure would be of short duration. Therefore, the only realistic potential exposure scenario for each of the land application sites is contact with sludge during the application process by a worker. However, to be conservative, it is assumed that a trespasser could contact constituents in soils. Both of these scenarios have been evaluated in the risk assessment.

There are no off-site residential receptors in the vicinity of the land application sites on the ORR; therefore, off-site impacts from land application of sludge have not been evaluated in this risk assessment.

Risk estimates for the two scenarios [on-site employee and trespasser (transient)] were made using default parameters provided by regulatory guidance to evaluate reasonable maximal exposure associated with land application sites.

1.3 RISK ASSESSMENT OVERVIEW

The risk assessment evaluates a single hypothetical land application site using the standard operating practices and receiving sanitary sludge that contains radionuclide and chemical concentrations that represent the measured sludge concentrations and soil concentrations at current land application sites. The approach and methodology used in this human health risk assessment are consistent with the guidance developed by the National Research Council (NRC). The NRC, established by the National Academy of Sciences to further scientific knowledge and to advise the federal government, developed the four-step paradigm for conducting health-based risk assessments (NRC 1983). This paradigm has been adopted by EPA as well as many other federal and state agencies. In accordance with the NRC recommendations, this risk assessment is organized into the following four steps:

1. Identification of Constituents of Concern (COCs)
2. Toxicity Assessment
3. Exposure Assessment
4. Risk Characterization

These four steps are described briefly below.

Identification of COCs. This step of the risk assessment process defines the COCs that are selected for more detailed evaluation in the remainder of the risk assessment. The data used to evaluate potential exposure are also presented in this section.

Toxicity Assessment. In the toxicity assessment, the relationship between the magnitude of exposure (dose) and the potential for occurrence of specific health effects (response) for each COC is evaluated. Both carcinogenic and noncarcinogenic effects are considered. The most current EPA-verified dose-response values are used when available.

Exposure Assessment. The objective of the exposure assessment is to evaluate the magnitude and frequency of potential exposure to COCs. Potentially exposed individuals, and the pathways by which they are potentially exposed, are identified based on the physical characteristics and uses of the site and surrounding area. The extent of a receptor's exposure is estimated by constructing “exposure scenarios” that describe the potential pathways of exposure to COCs and the activities and behaviors of individuals that might lead to contact with constituents in the environment.

Risk Characterization. In the risk characterization step, the results of the exposure assessment are combined with the results of the toxicity assessment to derive pathway-specific quantitative estimates of potential health risks. The estimates for each exposure pathway are then summed to give total risk estimates. Separate quantitative estimates of potential risk are derived for potentially carcinogenic effects and for noncarcinogenic effects.

2. IDENTIFICATION OF CONSTITUENTS OF CONCERN

Digested sludge that is to be applied to the land application areas is sampled and analyzed for organic, inorganic, heavy metal, and radionuclide compounds in an ongoing monitoring program based on state and federal requirements. Parameters such as pH, total percent solids, and percent volatile solids are monitored daily. Total gamma content is monitored each day that sludge is applied on the ORR, and quantitative radionuclide levels in sludge are measured weekly. Inorganic parameters such as nitrogen (ammonia, nitrate, nitrite, organic, and total nitrogen), potassium, phosphorus, and heavy metals are analyzed monthly. Organic compounds are analyzed in the digested sludge semiannually.

Many chemical and physical parameters monitor the efficacy of the sludge treatment system. For example, pH and total solids content allow treatment workers to judge whether the system is properly loaded or in danger of becoming too acid for effective microbial degradation. Similarly, measures of different forms of nitrogen monitor the degree to which the sludge is digested and the limits to which the resulting sludge can be spread on land and used as a fertilizer. These parameters are shown in ***Table G.1***. While measurable and vital to the operation of the treatment system, these analytes are nutrients for beneficial use and are not COCs to be addressed in this risk assessment.

During the biological digestion of sludge, microorganisms use the organic compounds present for growth, producing carbon dioxide or methane as a by-product. Therefore, with a properly working treatment system, most organic constituents would be reduced below detectable limits. For example, analyses for 1994 show that of the organic chemicals that were tested for in composite samples, aroclor-1254, chlordane, 4,4-DDE, and dieldrin were each reported at or slightly above detection in a single composite sample. Because, as a whole, the digestion process is working properly and reduces organic compounds below detectable limits, organic compounds are not considered to be of concern in this risk assessment.

Digested sludge was sampled monthly in 1993 and 1994 for heavy metals as required by 40 *CFR* 503 regulations for the land application of sludge. ***Table G.2.*** shows the maximum detected metal levels during 1993 and 1994 and compares them with the concentration limits in 40 *CFR* 503.13. In all samples, the heavy metals content of the sludge is below statutory limits. However, because some heavy metals can accumulate in the soil and bioaccumulate in biota, it is a conservative assumption for this risk assessment to consider these metals of potential concern.

The city of Oak Ridge sludge contains radionuclides that are generated from a variety of domestic and industrial sources. Although there are no applicable regulatory limits governing radionuclide levels in sewage sludge, composite sludge samples are monitored daily and analyzed weekly for radionuclides. The average yearly radionuclide levels from 1988 to 1993 are shown in ***Table G.3.*** Because of the conservative approach for this risk assessment, radionuclides with half-lives longer than 2 months (see ***Table G.3.*** for half-lives) were considered to be potential COCs because of their ability to accumulate.

Although some pathogens tend to concentrate in sludge during wastewater treatment, most are inactivated during anaerobic digestion (Sopper 1993). Inactivation varies by pathogen type, but, in general, the success of a treatment process to significantly reduce pathogens (as defined in 40 *CFR* 257) depends on its retention time and creating an environment particularly hostile to pathogenic organisms (EPA 1991b, 1991c, 1992b). For example, ova and cysts of parasites, which are more resistant to inactivation, may be reduced by only about 30-40% during anaerobic digestion (EPA 1991c); but poliovirus can be 98.8% inactivated (Bertucci et al. 1977) and bacteria typically reduced by 1-2 orders of magnitude (Pedersen 1981) [i.e., 5000 organisms reduced to 500 (1 order of magnitude) or even 50 (2 orders of magnitude)]. Application of sludge on plants and on the soil surface exposes remaining pathogens to desiccation and sunlight, further reducing the pathogens' survival rate.

Table G.1. Maximum concentrations of inorganic constituents in city of Oak Ridge POTW sewage sludge (1993-1994)

Inorganic parameter	Sampling frequency	Highest level detected in sludge in 1993 (mg/kg)	Highest level detected in sludge in 1994 (mg/kg)
Ammonia-nitrogen[a]	Monthly	60,000.00	30,000.00
Manganese	Monthly	1,260.0	1,710.0
Nitrate nitrogen[a]	Monthly	40.2	269.0
Nitrite nitrogen[a]	Monthly	8.8	30.7
Organic nitrogen	Monthly	40,000.0	49,800.0
pH	Daily	7.7	8.1
Potassium	Monthly	5,960.0	5410.0
Phosphorus	Monthly	36,200.0	36,800.0
Total Kjeldahl nitrogen[a]	Monthly	94,100.0	77,200.0
Total nitrogen[b]	Monthly	94,111.8	77,223.7
Total solids %	Daily	3.2%	3.3%
Volatile solids (% or TS)	Daily	63%	62%

Source: City of Oak Ridge 1994, 1995.

[a] These parameters are required to be sampled annually by National Pollutant Discharge Elimination System permit #TN0024155. Reporting of quantitative data is required, but limits are not specified.

[b] Total nitrogen represents the sum of total Kjeldahl and nitrate nitrogen.

Table G.2. Maximum concentrations of heavy metal constituents in city of Oak Ridge POTW sewage sludge (1993-1994) vs 40 *CFR* 503.13 ceiling concentration limits

Heavy metal	Mean concentration detected in sludge (mg/kg dry wt) 1996-2000	Maximum concentration detected in sludge (mg/kg dry wt) 1996-2000	40 *CFR* 503.13 Ceiling concentration limits (mg/kg dry wt)	Highest level detected as a percentage of regulatory ceiling
Arsenic	3.05	12.8	75	17%
Cadmium	4.23	19.4	85	22%
Chromium[a]	48.5	180	NA	NA
Copper	459.87	700	4300	16%
Lead	35.56	74	840	9%
Mercury	8.77	23	57	40%
Molybdenum	13.09	54	75	72%
Nickel	35.96	100	420	24%
Selenium	6.13	18.2	100	18%
Zinc	1157.77	1910	7500	26%

Source: City of Oak Ridge 1996-2000

[a] 40 *CFR* 503 limits for chromium have been excised by the EPA until further notice.

NA - Not Applicable

Table G.3. Historical radiological characterization of Oak Ridge sanitary sewage sludge (selected radionuclides)

		Average concentration, pCi/g dry weight						
Radionuclide	Half-life	1996	1997	1998	1999	2000	Mean	Maximum
Potassium-40	1.28×10^9 years	7.19	6.19	6.04	5.86	5.67	6.19	12.29
Cobalt-60	5.27 years	0.46	0.51	0.52	0.51	0.48	0.5	8.96
Cesium-137	30.2 years	0.8	0.31	0.36	2.07	1.88	1.08	9.24
Radium-228	5.8 years	1.13	1.01	0.97	0.84	0.62	0.91	1.69
Uranium-235	4.5×10^8 years	13.29	0.35	0.33	0.36	0.00	0.36	1.85
Uranium-238	4.5×10^9 years	0.75	8.0	10.58	7.62	2.58	8.41	50.95

Source: City of Oak Ridge

Reliable, EPA-approved risk assessment models are not available for quantifying human health risk from pathogens, but sludge application operator evidence and literature research show minimal risk from pathogens. Studies indicate that under EPA-approved sludge application practices, pathogens are not a health risk (Kowal 1982; EPA 1988, 1989a, 1991b, 1991c, 1992b; Sopper 1993). Land application of anaerobically digested sludges known to contain Salmonellae were found to present no apparent health risk to farm families when used in agricultural applications (Ottolenghi and Hamparian 1987). Cows grazed on anaerobically digested sludge-treated forage showed no bacterial, viral, or fungal infections in live animals or at necropsy, and incidence of intestinal parasites was the same in experimental and control cattle (Fitzgerald 1979). Land application of Chicago sludge on 6,000 ha resulted in no significant public health problems (Sedita et al. 1977) Reddy et al. (1985) also noted no significant health risk to humans or animals at sludge application rates of 2-10 metric tons/ha.

In summary, because of their potential to accumulate, heavy metals and radionuclides are potential COCs for evaluation of human health risk. Organics, inorganic nutrients, and pathogens are not considered COCs in this human health risk assessment.

3. TOXICITY ASSESSMENT

The purpose of the toxicity assessment is to identify the types of adverse health effects a COC may cause and to define the relationship between the dose of a COC and the likelihood or magnitude of an adverse effect (response). Adverse effects are characterized by EPA as carcinogenic or "noncarcinogenic," (i.e., potential effects other than cancer). Dose-response relationships are defined by EPA for oral exposure and for exposure by inhalation. Combining the results of the dose-response assessment with information on the magnitude of potential human exposure provides an estimate, usually very conservative, of potential risk.

Section 3.1 describes EPA's approach for developing noncarcinogenic dose-response values. Section 3.2 describes the carcinogenic dose-response relationships developed by EPA. Section 3.3 presents a discussion of radiological dose-response values and Sect. 3.4 discusses chemicals for which no EPA toxicity values are available. Sources of the published dose-response values used in this risk assessment include EPA's Integrated Risk Information System (IRIS) (http://www.epa.gov/iris/)

3.1 NONCARCINOGENIC DOSE-RESPONSE

Compounds with known or potential noncarcinogenic effects are assumed to have a dose below which no adverse effect occurs or, conversely, above which an adverse effect may be seen. This dose is the threshold dose. The threshold dose is called a No Observed Adverse Effect Level (NOAEL). The lowest dose at which an adverse effect occurs is called a Lowest Observed Adverse Effect Level (LOAEL). By applying uncertainty factors to the NOAEL or the LOAEL, References Doses (RfDs) for chronic exposures to chemicals with noncarcinogenic effects have been developed by EPA (1994a, 1994b). The uncertainty factors account for uncertainties associated with the dose-response relationship such as the effects of using an animal study to derive a human dose-response value, extrapolating from high to low doses, and evaluating sensitive subpopulations. Generally, a 10-fold factor is used to account for each of these uncertainties; thus, the total uncertainty factor can range from 10 to 10,000. In addition, an uncertainty factor or modifying factor of up to 10 can be used to account for "inadequacies in the database."

For chemicals with noncarcinogenic effects, an RfD provides reasonable certainty that no noncarcinogenic health effects are expected to occur even if daily exposures were to occur at the RfD level for a lifetime. RfDs and exposure doses are expressed in units of milligrams of chemical per kilogram body weight per day (mg/kg-day).

Table G.4. summarizes the dose-response information for the COCs with potential noncarcinogenic effects for the oral and inhalation routes of exposure. For each chemical, the dose-response value, and the reference for the dose-response value is presented. In addition, the target organ and critical effect upon which the dose-response value is based are also presented for each chemical.

In accordance with EPA National Center for Environmental Assessment policy, only chemicals with EPA-verifiable Reference Concentrations (RfCs) have been evaluated for noncarcinogenic effects following inhalation exposures. Dose-response values for the inhalation route of exposure are provided by the EPA as RfCs, expressed as milligrams of compound per cubic meter of air (mg/m^3). In order to use these dose-response values to calculate an average daily exposure dose, the RfCs are converted to RfDs, expressed as the corresponding inhaled dose in mg/kg-day. The conversion from RfC to RfD follows the formula cited in HEAST (EPA 1994b):

$$\text{RfC } (mg/m^3) \times (1/70 \text{ kg}) \times (20 \text{ } m^3/\text{day}) = \text{RfD } (\text{mg/kg-day}).$$

Table G.4. Dose-response data for COCs with potential noncarcinogenic effects

Compound	CAS[a]	Inhalation RfD (mg/kg-day)	Reference (last verified)	Oral RfD (mg/kg-day)	Reference (last verified)	Target organ system
Arsenic	7440382	NA[b]	—	3.0E-4	IRIS (1/01)	Skin; keratosis
Cadmium	7440439	NA	—	5.0E-4	IRIS (1/01)	[c]
Chromium-VI	7440473	NA	—	5.0E-3	IRIS (1/01)	No adverse effects observed
Chromium-III	7440473	NA	—	1.5E+0	IRIS (1/01)	
Copper	7440508	NA	—	NA	IRIS (1/01)	Gastrointestinal
Lead	7439921	NA	—	NA	—	CNS[d]; blood
Mercury	7439976	8.57E-5	IRIS (1/01)	NA	—	Kidney effects
Molybdenum	7439987	NA	—	5.0E-3	IRIS (1/01)	Urine; joints; blood
Nickel	7440020	NA	—	2.0E-2	IRIS (1/01)	Decreased body and organ weight
Selenium	7782492	NA	—	5.0E-3	IRIS (1/01)	Whole body; selenosis
Zinc	7440666	NA	—	3.0E-1	IRIS (1/01)	Blood; anemia

[a] Chemical Abstracts Service Registry Number.

[b] NA = Not available; inhalation RfD is not listed in IRIS database or HEAST tables (EPA 1994b).

[c] The oral RfD for cadmium was derived by EPA using a pharmacokinetic model assuming 5% absorption from water and 2.5% absorption from food/soil.

[d] CNS = central nervous system.

3.2 CARCINOGENIC DOSE-RESPONSE

The underlying assumption of regulatory risk assessment for compounds with known or assumed potential carcinogenic effects is that no threshold dose exists. Thus, the characterization assumes that there is some finite level of risk associated with each nonzero dose. The EPA methodology is to extrapolate dose-response relationships observed at the relatively high doses used in animal studies to the low dose levels encountered by humans in environmental situations. The mathematical models assume no threshold and use both animal and human data to develop a potency estimate for a given compound. The potency estimate, called a cancer slope factor (CSF) is expressed in units of (mg/kg-day)$^{-1}$.

Table G.5. summarizes the oral and inhalation dose-response information developed by EPA for potentially carcinogenic COCs identified for this assessment. For each chemical, the CSF and its reference are provided.

3.3 RADIATION TOXICITY

The potential health effects associated with exposure to radionuclides at the land application sites are due to low-level ionizing alpha, beta, and gamma radiation emitted by the radionuclides in sanitary sewage sludge. The primary effects include an increase in the occurrence of cancer in irradiated individuals and possible genetic effects that may occur in future generations. The risk of serious genetic effects is much lower than the risk of cancer induction (EPA 1989b). Therefore, genetic effects are not the focus of this toxicity assessment, and radiological risks are evaluated only with respect to incremental cancer probabilities per EPA guidance (EPA 1989b).

The toxicity of the various radionuclides found in sludge is based on:

- the types and energies of radiation they emit;
- the biological importance of the organs/tissues being irradiated;
- the radiological sensitivity of the organs/tissues being irradiated; and
- for internal exposure only, metabolic behavior in the body and biological retention characteristics in the body.

Radiation-induced health effects for humans have been confirmed only at relatively high doses or high dose rates with large populations. Exposure to a high dose of radiation (e.g., a thousand times the average annual background dose rate) during a short period of time (a few hours) produces detrimental effects in all the organs and systems of the body. For low doses, health effects are presumed to occur but can only be estimated statistically. Risk estimates are strictly applicable to large populations, because the appearance of health effects after an exposure is a chance event. For purposes of radiological impact assessment, the health effects are measured by cancer incidence in the exposed population. However, risk estimates in the low-dose range are uncertain because of extrapolation from high doses and because of assumptions made on dose-effect relationships and the underlying mechanisms of carcinogenesis.

Table G.5. Dose-response data for COCs with potential carcinogenic effects

Compound	CAS[a]	Weight of evidence[b]	Oral slope factor $(mg/kg\text{-}day)^{-1}$	Reference (last verified)	Inhalation slope factor $(mg/kg\text{-}day)^{-1}$	Reference (last verified)
Arsenic	7440382	A	1.5E+0	IRIS (1/01)	1.51E+1	IRIS (1/01)
Cadmium	7440439	B1	NA[c]	—	6.3E+0	IRIS (1/01)
Chromium-VI	7440473	A	NA	—	4.2E+1	IRIS (1/01)
Copper	7440508	D	NA	—	NA	IRIS (1/01)
Lead	7439921	B2	NA	—	NA	IRIS (1/01)
Mercury	7439976	D	NA	—	NA	IRIS (1/01)
Molybdenum	7439987	—	NA	—	NA	IRIS (1/01)
Nickel	7440020	A	NA	—	NA	IRIS (1/01)
Selenium	7782492	D	NA	—	NA	IRIS (1/01)
Zinc	7440666	D	NA	—	NA	IRIS (1/01)

[a] Chemical Abstracts Service Registry Number.

[b] Weight of Evidence Classifications:

A = Human carcinogen (sufficient evidence of carcinogenicity in humans)

B1 = Probable human carcinogen (limited evidence of carcinogenicity in humans)

B2 = Probable human carcinogen (sufficient evidence of carcinogenicity in animals, with inadequate or lack of evidence of carcinogenicity in humans)

C = Possible human carcinogen (limited evidence of carcinogenicity in animals, and inadequate or lack of evidence of human data)

D = Not classifiable as to human carcinogenicity

[c] NA = Not available; chemical is not listed in IRIS database or HEAST tables as a carcinogen (EPA 1994b).

Radiation effects in the exposed population cannot be readily identified because radiogenic cancers are indistinguishable from those resulting from other factors. Studies of populations chronically exposed to low-level radiation, such as those residing in regions of elevated natural background, have not shown consistent evidence of an associated increase in the risk of cancer.

Alpha, beta, and gamma radiations are released during the radioactive decay process. Each type of radiation differs in its physical properties and in its ability to induce damage to biological tissue. The BEIR IV report (NRC 1988) addresses the risk from alpha radiations. Alpha particles are an internal exposure hazard rather than an external hazard because they are unable to penetrate the dead skin cell layer of the body to reach living tissue. Within the body alpha particles are the most effective of the three types of radiation in damaging cells because they have high linear energy transfer (LET), (i.e., their energy is completely absorbed by tissue within a short distance). High LET radiation is more damaging to cells than low LET radiation. The BEIR V report (NRC 1990) addresses the risk from low LET radiation such as gamma and beta particles. Beta particles are primarily an internal hazard; however, in cases of external skin exposure, energetic beta particles can penetrate living skin cells, representing an external hazard as well. Beta particles deposit less energy to small volumes of tissue than alpha particles and, therefore, induce much less damage than alpha particles. Gamma radiation is primarily an external hazard because it can penetrate tissue and reach internal organs without being taken into the body.

EPA has developed guidance for radiological risk assessment consistent with existing guidance for assessing chemical carcinogenic risks (CSFs per unit intake) (EPA 1989b). ***Table G.6.*** summarizes potency factors used in the calculation of potential risk from exposure to radionuclides.

3.4 CHEMICALS FOR WHICH EPA TOXICITY VALUES ARE NOT AVAILABLE

Because of the uncertainties in the relationship between exposure to lead and biological effects (dose-response), it is unclear whether the noncarcinogenic effects of lead exhibit a threshold response. Therefore, an RfD for lead is not available. Lead exposure health effects of most concern are impaired mental and physical development in young children.

Because most human health effects data are based on blood lead (Pb) concentration, EPA has developed a quantitative method for estimating detrimental environmental lead levels in children using an uptake biokinetic model. Several EPA regional and state models exist to address situations where adults are exposed. Because the interim soil cleanup level of 400 ppm for residential sites and 1000 ppm for industrial sites recommended by Office of Emergency and Remedial Response directive 9355.4-12 (EPA 1994c) is so much greater than the maximum measured concentration in sludge or soil, an evaluation of blood lead levels was not done in this assessment.

Table G.6. Radionuclide potency factors

Radionuclide	External radiation slope factor 1/year per pCi/g	Inhalation slope factor 1/pCi	Ingestion slope factor 1/pCi
Cobalt-60	9.8E-6	6.9E-11	1.9E-11
Cesium-137 + D	2.1E-6	1.9E-11	3.2E-11
Potassium-40	6.1E-7	7.5E-12	1.3E-11
Radium-228 + D	6.7E-6	2.7E-9	3.0E-10
Uranium-235 + D	2.7E-7	1.3E-8	4.7E-11
Uranium-238 + D	5.7E-8	1.2E-8	6.2E-11

Source: HEAST (EPA 1995).

4. EXPOSURE ASSESSMENT

4.1 IDENTIFICATION OF POTENTIAL RECEPTORS

Receptors considered for exposure to the sludge include an employee who would load the sludge and spread it on the application areas and a transient who would be incidentally exposed to the soil shortly after sludge application. Currently, an employee of the city of Oak Ridge POTW applies sludge to the designated soil areas on a daily basis and is considered as the maximally exposed individual. Although there is restricted access to the application areas on the ORR, a transient scenario was considered. Land use at the ORR is anticipated to remain industrial; therefore, a hypothetical receptor residing on an application site in the future was not considered in this assessment.

4.2 IDENTIFICATION OF EXPOSURE PATHWAYS

A complete exposure pathway consists of the following four elements: (1) a source and mechanism of contaminant release to the environment, (2) an environmental transport mechanism for the released contaminants, (3) a point of human contact with the contaminated medium, and (4) a route of entry for the contaminant into the human receptor at the exposure point. The sludge itself can be considered the exposure point without a release to any other medium. The soil, as the receiving medium, can also be an exposure point following sludge application. An integration of the source, its release, fate and transport mechanisms, exposure points, and exposure routes is evaluated for complete exposure pathways. If any of these elements is missing, the pathway is incomplete and will not be considered further in this risk evaluation.

For the city of Oak Ridge POTW sludge, the sludge itself is the source of the contamination. It can be released into the air during application procedures, and it is released into the soil as it is applied. Potential exposure routes to human receptors include inhalation of suspended sludge particles, incidental ingestion of sludge, and dermal contact when handling contaminated equipment or soil.

Because of uncertainties associated with the quantification of dermal exposure (EPA 1992a) and because dermal exposure is considered to be less than that by direct ingestion for the constituents included in this risk assessment, only inhalation and ingestion pathways and external radiation are considered quantitatively in this assessment. The city uses a gamma counting system to screen sludge each day that material is hauled to the ORR for application to ensure that external exposures are below the approved action limits. Therefore, external exposure to radionuclides in sludge is not evaluated for the worker. Because radionuclides can be concentrated in soil over time, external exposure to gamma radiation from the soil is included for evaluation of the trespasser.

4.3 MEDIA EXPOSURE CONCENTRATIONS

Radionuclide and chemical exposure point concentrations in sludge are shown in ***Table G.7.*** Maximum and average measured concentrations from sampling events in 1994 were used in the risk assessment. Mean and maximum radionuclide and chemical air concentrations (pCi/m^3 or mg/m^3) were conservatively estimated from the sludge concentration by:

$$C_{air} = PL * C_{soil} * CF$$

where

PL = Particulate loading (50 μg/m^3),
C_{soil} = Concentration of chemical or radionuclide in soil (mg/kg or pCi/g), and
CF = Conversion factor (1E-9 kg/μg or 1E-6 g/μg).

It is conservatively assumed that air particulates during application are equal to the National Ambient Air Quality Standard for the annual average respirable portion (PM_{10}) of suspended particulate matter of 50 μg/m^3. It is further assumed that 100% of the particulates have the same contaminant concentration as the soil value.

Table G.7. Exposure point concentrations in sludge and air

Constituent	Maximum sludge concentration	Maximum air concentration	Mean sludge concentration	Mean air concentration
		Radionuclides		
	pCi/g	pCi/m^3	pCi/g	pCi/m^3
Cobalt-60	8.96	4.5E-04	0.50	2.5E-05
Cesium-137	9.24	4.6E-04	1.08	5.4E-05
Potassium-40	12.29	6.1E-04	6.19	3.1E-04
Radium-228	1.69	8.5E-05	0.91	4.6E-05
Uranium-235	1.85	9.3E-05	0.36	1.8E-05
Uranium-238	50.96	2.5E-03	8.41	4.2E-04
		Chemicals		
	mg/kg	mg/m3	mg/kg	mg/m3
Arsenic	12.8	6.40E-07	3.05	1.53E-07
Cadmium	19.4	9.70E-07	4.23	2.12E-07
Chromium	180	9.00E-06	48.52	2.43E-06
Copper	700	3.50E-05	459.87	2.30E-05
Lead	74.6	3.73E-06	35.56	1.78E-06
Mercury	23	1.15E-06	8.77	4.39E-07
Molybdenum	54	2.70E-06	13.09	6.55E-07
Nickel	100	5.00E-06	35.96	1.80E-06
Selenium	18.2	9.10E-07	6.13	3.07E-07
Zinc	1910	9.55E-05	1155.77	5.79E-05

The 1994 measured maximum soil concentrations for radionuclides and chemicals and the estimated air concentrations are shown in ***Table G.8.*** The values shown represent the soil exposure point concentrations used in evaluating potential exposure of a trespasser to accumulated concentrations in soil.

4.4 ESTIMATION OF POTENTIAL EXPOSURE DOSES

Chemical intake estimates are based on EPA methodology presented in *Risk Assessment Guidance for Superfund* (EPA 1989b) and related guidance (EPA 1991a). Radiological dose estimates were calculated using Residual Radioactivity (computer model) (RESRAD) in accordance with DOE Order 5400.5. For the worker, intakes and radiological doses were calculated for incidental sludge ingestion and inhalation of sludge particulates. The average and the maximum exposure point concentrations were used to provide a range of potential exposure.

Incidental ingestion of soil and inhalation of soil particulates as well as direct irradiation from the application site were evaluated for the trespasser. Maximum measured soil concentrations from 1996-2000 were used.

The assumptions and calculations used to estimate chemical and radiological intakes for the receptors are shown in ***Tables G.9.*** and ***G.10.*** Exposure time, frequency, and duration determine the total time that a receptor is exposed to the contaminant source. Exposure time is the number of hours per day that a receptor is present at a specific exposure point. Exposure frequency is the number of days per year that the exposure occurs, and exposure duration is the total number of years over which exposure occurs.

Based on current activity patterns, an employee is expected to be exposed to sludge through pumping, loading, or application activities for no more than 4 hours of each work day. An employee is assumed to work with sludge 250 days/year for 25 years (EPA 1989b). Because the application areas on the ORR have restricted access, trespassers were conservatively assumed to have exposure once a month for 1 hour each time over a 10-year period. Rates for incidental soil ingestion and inhalation are conservative based on maximal levels recommended in EPA guidance (EPA 1991a).

The radiological dose for both the employee exposed to maximal and average concentrations of radionuclides in sludge is 0.143 mrem/year and 0.067 mrem/year, respectively, (see ***Table G.11.***) well below a 10 mrem/year threshold, or an order of magnitude reduction of the primary public dose limit of 100 mrem/year from all sources of radiation as described in DOE Order 5400.5, Chap. II.

Table G.8. Exposure point concentrations in soil and air

Constituent	Maximum soil concentration	Maximum air concentration
Radionuclides	**pCi/g**	**pCi/m^3**
Cobalt-60	0.64	3.2E-5
Cesium-137	0.71	3.6E-5
Potassium-40	ND	ND
Radium-228	ND	ND
Uranium-235	0.89	4.5E-05
Uranium-238	2.04	1.0E-04
Metals	**mg/kg**	**mg/m^3**
Arsenic	12.8	6.40E-07
Cadmium	19.4	9.70E-07
Chromium	180	9.00E-06
Copper	700	3.50E-05
Lead	74.6	3.73E-06
Mercury	23	1.15E-06
Molybdenum	54	2.70E-06
Nickel	100	5.00E-06
Selenium	18.2	9.10E-07
Zinc	1910	9.55E-05

Table G.9. Incidental sludge ingestion

Parameter (unit)	Value: Employee	Value: Trans ient	Reference
Sludge ingestion rate (mg/day)	50	50	EPA 1991a
Fraction ingested from contaminated source (unitless)	0.5	1.0	Conservative judgment
Exposure frequency (day/year)	250		EPA 1989b, based on days employee works on site per year
		12	Conservative judgment
Exposure duration (years)	25		EPA 1989b, based on 90th percentile for employees
		10	Conservative judgment
Body weight (kg)	70	70	EPA 1989b, EPA 1991a, combined mean of male and female body weights
Carcinogen averaging time (days)	25,550	25,55 0	EPA 1990, equivalent to 70-year lifetime exposure at 365 days/year
Noncarcinogen averaging time (days)	9,125	3,650	EPA 1991a, exposure duration × 365 days/year

Equation for ingestion of chemicals in soil and sludge (EPA 1989a):

$$Intake\ (mg/kg\text{-}d) = \frac{C_s \times IR_s \times CF \times FI \times EF \times ED}{BW \times AT}$$

where:
- C_s = chemical soil concentration in soil (mg/kg),
- IR_s = soil ingestion rate (mg soil/day),
- CF = conversion factor (10^{-6} kg/mg),
- FI = fraction ingested from contaminated source (unitless),
- EF = exposure frequency (days/year),
- ED = exposure duration (year),
- BW = body weight (kg), and
- AT = averaging time (day).

Equation for ingestion of radionuclides in soil and sludge (Gilbert et al. 1989):

$$D_i = C_{soil,i} \times IR_s \times FI \times EF \times ED \times CF_m$$

where:

D_i = intake from radionuclide i (pCi),

$C_{soil,i}$ = soil concentration of radionuclide i (pCi/g),

IR_s = soil ingestion rate (mg/day),

FI = fraction ingested from the contaminated source (unitless),

EF = exposure frequency (days/year),

ED = exposure duration (year), and

CF_m = conversion factor, 10^{-3} g/mg.

Table G.10. Inhalation of particulates

Parameters (unit)	Value: Employee	Value: Transient	Reference
Inhalation rate of airborne particles (m^3/hour)	20	20	EPA 1991a; Inhalation rates based on combination of rates for light, moderate, and heavy activity for an 8-hour workday
Exposure time outdoors (hours/day)	4	1	Site-specific observation (based on current activity for employee). Professional judgment for transient.
Exposure frequency (days/year)	250	12	EPA 1989b, number of days employee works on site per year
Exposure duration (years)	25	10	EPA 1990, based on 90th percentile for employee; best judgment
Body weight (kg)	70	70	EPA 1989b
Carcinogen averaging time (days)	25,550	25,550	EPA 1990, equivalent to 70-year lifetime exposure at 365 days/year
Noncarcinogen averaging time (days)	9,125	3,650	EPA 1991a, exposure duration × 365 days/year

Equation for inhalation (chemicals) (EPA 1989a):

$$Intake\ (mg/kg\text{-}d) = \frac{C_{air} \times IR \times ET \times EF \times ED}{BW \times AT}$$

where: C_{air} = contaminant concentration in air (mg/m^3), derived from chemical concentration in soils,
IR = inhalation rate (m^3/hour),
ET = exposure time (hours/day),
EF = exposure frequency (days/year),
ED = exposure duration (year),
BW = body weight (kg), and
AT = averaging time (days).

Equation for inhalation of particulates (radionuclides) (Gilbert et al. 1989):

$$D_i = C_{air,i} \times IR \times EF \times FT \times CF_t$$

where: D_i = intake from radionuclide i (pCi),

$C_{air,i}$ = air concentration of radionuclide i (pCi/m^3) (based on soil concentration),

EF = exposure frequency (days/year) (e.g., 4 hours/day × 250 days/year × days/24-hours = 41.7 days/year),

ED = exposure duration (year),

IR = inhalation rate (m^3/hour), and

CF_t = conversion factor (24 hours/day).

5. RISK CHARACTERIZATION

5.1 METHODOLOGY

For the chemical assessment, risk is defined as the lifetime probability of cancer incidence for carcinogens and the estimate of exceeding toxic effect thresholds for noncarcinogens. For the radiological assessment, risk is defined as the lifetime probability of cancer morbidity and does not include genetic or noncarcinogenic effects.

EPA does not use a probabilistic approach to estimate the potential for noncarcinogenic health effects (EPA 1989b). The potential for noncarcinogenic adverse health effects is evaluated as the ratio of the daily intake for the exposure period over the RfD. This ratio is the hazard quotient (HQ). The RfD is a provisional estimate of the daily exposure to the human population, including sensitive subgroups (with uncertainty spanning perhaps an order of magnitude). The RfD is a reference dose below which appreciable risk of negative health effects during a lifetime for chronic exposure would not be expected to occur (EPA 1989b). Although EPA has derived RfDs for both chronic and subchronic exposure, only chronic exposure of over 7 years is considered in this health assessment.

The noncancer HQ assumes that there is a level of exposure (the RfD) below which it is unlikely for even sensitive populations to experience adverse noncarcinogenic health effects (EPA 1989b). The HQs for each chemical addressed in the intake and exposure pathway are summed to obtain the hazard index (HI), which allows assessment of the overall potential for noncarcinogenic health effects. An HI greater than one (HI>1) has been defined as the level of concern for potential adverse noncarcinogenic health effects (EPA 1989b).

Cancer risks are estimated as the incremental probability of an individual developing cancer over a lifetime as a result of pathway-specific exposure to carcinogenic contaminants. Results of the cancer risk estimates can be compared with the acceptable risk range of 10^{-6} to 10^{-4} (or 1 in 1,000,000 to 1 in 10,000) that is the goal of EPA outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP).

The risk to an individual resulting from exposure to chemical or radiological carcinogens is expressed as the increased probability of a cancer occurring over the course of a lifetime. The increased cancer risk is calculated by estimating the daily intake of a chemical carcinogen averaged over a lifetime multiplied by a contaminant-specific CSF. Oral and inhalation pathway-specific CSFs have been derived for certain carcinogens; some carcinogens do not have a CSF available or are presently under review by EPA. All CSFs used in the chemical risk estimate calculations were obtained from EPA's IRIS (EPA 1994a) or HEAST (EPA 1994b). RESRAD (v.5.61) was used to calculate radiological risks (Yu et al. 1993); chemical risks were calculated following EPA guidance (EPA 1989b).

The CSF converts estimated daily intakes averaged over a lifetime of exposure directly to the incremental risk of an individual developing cancer (EPA 1989b). The carcinogenic risk estimate is generally an upper-bound estimate because the CSF is typically derived as the upper 95% confidence level of the probability of response based on experimental animal data (EPA 1989b). Thus, EPA is reasonably confident that the “true risk” will not exceed the risk estimate derived through use of the CSF and is likely to be less than that predicted using CSFs (EPA 1989b).

5.2 RISK AND HAZARD INDEX ESTIMATES

Table G.11. summarizes the carcinogenic risk from radionuclides in sludge and soil to the worker and trespasser. The risk to workers is estimated to be 4×10^{-7} and 2×10^{-7} for the maximum and mean sludge concentrations, respectively, which are below the EPA target range of 10^{-4} to 10^{-6}. The risk to transients from exposure to soil is estimated to be 1×10^{-7}, which is also below the EPA target range.

Table G.11. Summary of radiological exposure

Employee				**Transient**	
Dose (mrem/year)		**Cancer risk**		**Dose (mrem/year)**	**Cancer risk**
Mean	Maximum	Mean	Maximum		
0.0669	0.143	2E-7	4E-7	0.016	1E-7

Carcinogenic health effects from exposure to heavy metals are summarized in ***Table G.12.*** The estimated cancer risks for both the employee exposed to maximum concentrations in sludge and trespasser receptors exposed to soil are 6.33×10^{-6} and 1.67×10^{-7}, respectively, which are within the EPA target range.

Hazard quotients from exposure to heavy metals for both employees and transients are summarized in ***Table G.12.*** The HQ for both ingestion and particulate inhalation pathways is less than the threshold of one for both receptors. Exposure to noncarcinogenic contaminants in the sludge and soil is not likely to result in adverse health effects under the employee or trespasser scenarios.

Particulate inhalation and ingestion both contribute to the risk for both chemicals and radionuclides. Risks to employees could be reduced further by procedural controls during spraying of sludge (e.g., closing the truck window, wearing a mask). The major contributing pathway to risks to trespassers on the sludge application sites is external irradiation from exposure to cobalt-60 mixed into the soil. The likelihood of a trespasser on these sites is very low, so the risks in this analysis may be overstated. Additionally, because cobalt-60 has a relatively short half-life, the potential risks would decrease over time after application ceases.

Table G.12. Chemical Risk and Hazards

	Employee				Transient			
	HQ		Cancer risk		HQ		Cancer risk	
Pathway	CrIII	CrVI	CrIII	CrVI	CrIII	CrVI	CrIII	CrVI
Ingestion	1.73e-02	2.67e-02	3.67e-06	3.67e-06	2.07e-04	2.57e-04	8.45e-08	8.45e-08
Inhalation	5.14e-04	4.15e-01	2.12e-06	2.67e-06	4.55e-06	5.52e-03	6.29e-09	8.21e-08
Total	1.78e-02	4.42e-01	5.79e-06	6.33e-06	2.07e-04	5.79e-03	9.08e-08	1.67e-07

The model parameter with the most significant impact on risk values and potential health effects is the valence state of chromium. The valence state is not known, therefore, the carcinogenic risks and health effects are estimated for both valence states.

6. UNCERTAINTY ANALYSIS

The risks calculated in this assessment are single point estimates of risk rather than probabilistic estimates. Therefore, it is important to discuss uncertainties inherent in the risk assessment in order to place the risk estimates in proper perspective. Uncertainties can be associated with sampling data adequacy, selection of potential COCs, exposure assessment variables, and toxicity values.

The sludge is composited and analyzed at regular time intervals for the various chemical parameters. Changes in customer activities (e.g., an increase or decrease in nuclear medicine studies) can affect the character of the sludge. These changes in sludge composition could increase the uncertainty that a sample is representative of an "average" sludge. However, since the sampling is conducted frequently (daily scanning when sludge is being applied on the ORR, weekly sampling for radionuclides, monthly for heavy metals, semi-annually for organics) and the levels of detected analytes are relatively constant among samples, the uncertainty in sampling data adequacy is low.

Uncertainty is inherent in the selection of potential COCs for analysis and is associated with a number of factors. The identification of potential COCs for a human health evaluation relies on both data from the monitoring program and the application of a selection process. Considerable data on the sludge composition have been collected over the years under the city of Oak Ridge's monitoring program. The monitoring program is based on federal and state requirements for chemical components and on knowledge of its industrial customers for radiological components. The monitoring program is comprehensive, hence the uncertainty associated with the identification of potential COCs for analysis is low.

The variables used for the exposure assessment were extremely conservative and could lead to an overestimation of risk. Maximal and average values were used for the exposure point concentrations. The exposure intake assumptions were generally the EPA default values. Employee receptors were assumed to be directly underneath the spray of sludge during application, breathing at a rate indicative of heavy activity. Workers are typically in the vehicle and are taking precautions to avoid exposure. The conservative nature of the assessment results in an overestimation of potential risk.

Standard risk estimate factors were used to estimate the hazards associated with exposure to the potential COCs. There were several identifiable potential COCs for which there were no toxicity factors or slope factors, precluding their inclusion in quantitative risk estimates. Additionally, radiological contaminants with half-lives <2 months (beryllium-7 and iodine-131) were not selected for consideration in this assessment. The resulting risk estimates do not include the incremental chemical-specific risks from these potential COCs and, therefore, may underestimate risk, although the magnitude of this underestimation is not quantifiable.

Some of the procedures used and uncertainties inherent in the human health risk assessment process may tend to underestimate potential risk. However, assumptions built into this assessment tend to overestimate rather than underestimate potential risks, including conservative assumptions for exposure point concentrations and exposure scenarios.

7. SUMMARY AND CONCLUSIONS

The radiological dose (***Table G.11.***) that an employee might receive from exposure to sludge is very low and consistent with health physics monitoring of current POTW employees involved in sludge handling and application procedures. Monitoring of employees has shown no detectable exposure to radionuclides (Mobley 1993), and there is anecdotal information that the sludge workers are in good health.

Combined chemical and radiological risks to employees exposed to sludge during the land application process are minimal and are within the EPA target range for excess lifetime cancer risk. These estimates of risk to human health should not be taken to represent absolute risk; rather, they represent the most important sources of potential relative risk from handling sludge.

Noncarcinogenic risks were estimated to be <1, for both the worker and the trespasser, indicating that no adverse effects would be expected from exposure to sludge or sludge-amended soils.

Potential carcinogenic risk to receptors infrequently contacting soils to which sludges have been applied was within the EPA target risk range. The land application areas on the ORR currently have limited access, and it is assumed that sludges will be applied to meet statutory and/or risk-based limits. Future changes in land use or access restrictions would not result in significant risks to future receptors, assuming sludge application limits were followed.

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